

REMARKS

Claims 1-24 are pending in the application. The claims have been amended to place them in more conventional US patent claim format. No new matter has been added. Favorable consideration is requested.

Once again, respectfully stated, the Office Action includes errors and inconsistencies and is believed to contain rejections that should be withdrawn.

In paragraph no. 3 on pages 2-5 of the Detailed Action, claims 1, 3, 5-6, 8-9, 12, 14, 15, 17-20 and 22-23 stand rejected under 35 U.S.C. 103 as allegedly being "anticipated" by:

1. Bonsall (USP 5865766 -- referred to by the Examiner as B) in view of
2. Blum (USP 4268268 – referred to by the Examiner as C), and further in view of
3. Pfeiffer (USP 5902253 -- referred to as P by the Examiner).

In response, applicant requests the withdrawal of this rejection because it is legally improper for an anticipation rejection to be based on multiple references. Indeed, Bonsall (the first reference) does not apply to the field of peritoneal dialysis – which is clearly the field of the claimed invention. In this regard, the claims are all directed to "peritoneal dialysis" in the preamble as well as the body of the claims. Bonsall does not. Nor do Blum or Pfeiffer. As a result, there can be no anticipation.

Nor can there be any *prima facie* case of obviousness because the first reference does not concern peritoneal dialysis, nor do the other two references concern peritoneal dialysis. Thus, no one would or could modify the primary reference with the features of the other references in order to arrive at the claimed peritoneal dialysis invention that requires:

a peritoneal dialysis sampling system adapted to automatically sample at specific time intervals volumic fluid fractions of a dialysate contained in a peritoneum of a patient in order to evaluate peritoneal membrane characteristics and/or improve peritoneal dialysis for a given patient,

wherein said peritoneal dialysis sampling system comprises:

a series of sampling containers,

pumping means, and

a series of valves adapted to direct a certain quantity of

each fluid fraction sample of dialysate taken from a

peritoneum of a patient to a specific sampling container in

the series of sampling containers.

Moreover, in response to applicant's patentability arguments of July 13, 2010, the Examiner has simply replied with the following **two quoted general comments** on page 8 of the Office Action:

1. The Examiner states: "Since it contains all of applicant's claimed invention and is capable of performing the task, the rejection is proper."

What is "it" in this phrase? Is "it" one of the three cited references? Not one of the references is capable of automatically sampling at specific time intervals volumic fluid fractions of a dialysate contained in a peritoneum of a patient in order to evaluate peritoneal membrane characteristics and/or improve peritoneal dialysis for a given patient, and not one of the references has all of the structure, features, and functions stated in the claims.

2. The Examiner states: "In this case, the reduction of weight provides a benefit to the primary reference."

What does this have to do with the claimed invention and applicant's arguments for patentability? There is no "weight" mentioned in the claims. Moreover, the primary reference is not a peritoneal dialysis system so there is no motivation for anyone in the peritoneal dialysis field to take the Bonsall device and modify it to arrive at the claimed invention – without improper hindsight.

For at least the foregoing reasons, the rejection should be withdrawn, i.e., it is defective and does not present a proper anticipation rejection or a prima facie case of obviousness.

Once again (like in the last Office Action), Applicant believes that the last two rejections in the Office Action (paragraph nos. 4 and 5 in the Detailed Action) were incorrectly copied from the last Office Action and that those paragraphs were incorrectly copied from the previous Office Action. And, once again, Applicant believes that these rejections have been withdrawn by the Examiner because the Examiner has stated at the bottom of page 7 of the Detailed Action:

"Applicant's arguments filed 7/13/10 have been fully considered are persuasive."

Moreover, the Office Action did not address the applicant's arguments of 7/13/10 concerning the two rejections. Thus, applicant believes that the rejections of paragraph nos. 4 and 5 have already been addressed and overcome for at least the following reasons.

In paragraph no. 4 on pages 5-6 of the Detailed Action, claims 2, 4, 13, 16, and 21 stand rejected under 35 U.S.C. 103(a) as allegedly being "anticipated" by

1. B and
2. P in view of
3. Suzuki (USP 6595948 -- referred to as S by the Examiner).

In response, applicant requests the withdrawal of this rejection because an anticipation rejection cannot be based on multiple references.

In addition, neither of the first two cited references (Bonsall nor Pfeiffer) apply to the field of peritoneal dialysis – which is the field of the invention. As noted above, the claims are all directed to “peritoneal dialysis” in the preamble as well as the body of the claims. Bonsal and Pfeifer do not. As a result, there can be no anticipation.

Nor can there be any *prima facie* case of obviousness because the first reference and the second reference do not concern peritoneal dialysis; thus, no one would or could modify either of them to arrive at the claimed invention – without improper hindsight. Indeed, one skilled in the art of peritoneal dialysis would not and could not combine Bonsal and Pfeifer as the primary references with Suzuki in any fashion in order to arrive at the claimed peritoneal dialysis system that requires a specific peritoneal dialysis configuration. Claim 2 concerns a peritoneal dialysis system comprising an automatic peritoneal dialysis sampling system according to claim 1, a supplying line and supplying means for supplying dialysis fluid to a peritoneal cavity, a draining line, draining means for draining the fluid from said peritoneal cavity, connecting means for allowing a connection to a Y-site on the draining line which is situated between the patient peritoneum and the draining means of the peritoneal dialysis system.

For at least the foregoing reasons, the rejection should be withdrawn, i.e., it is defective and does not present a proper anticipation rejection or a *prima facie* case of obviousness.

In paragraph no. 5 on pages 6-7 of the Detailed Action, claims 7, 10 and 11 stand rejected as allegedly being obvious over B and P in view of Klein (USP 4244787). In response, applicant requests the withdrawal of this rejection because it fails to state a *prima facie* case of obviousness.

As noted in the foregoing paragraphs (which are applicable here because rejected dependent claims 7, 10 and 11 include all of the features of claims 1 and 2), neither Bonsall nor Pfeiffer apply to the field of peritoneal dialysis – which is the field of the invention. In this regard, independent claim 1, dependent claim 2, and the rejected dependent claims 7, 10 and 11 are directed to a specific peritoneal dialysis system. Bonsal and Pfeifer do not. Thus, one skilled in the art of peritoneal dialysis would not combine Bonsal and Pfeifer as the primary references with Klein as the secondary reference in order to arrive at the claimed peritoneal dialysis system that requires a specific peritoneal dialysis configuration and components.

Fairly stated, the rejection does not explain how it would be reasonably apparent to combine the references and arrive at the claimed invention. This confirms that the rejection does not comply with the Supreme Court's pronouncements in *KSR*. As stated by the Supreme Court in *KSR*, there must be a “reasonably apparent” way to combine references that would yield the claimed invention. In this case, the primary references do not even relate to peritoneal dialysis and, therefore, it would not be reasonably apparent to combine these primary references with the Klein reference in any fashion to arrive at the claimed invention, which requires, among other things:

an automatic peritoneal dialysis sampling system adapted to automatically sample at specific time intervals volumic fractions of a dialysate contained in a peritoneum of a patient in order to evaluate peritoneal membrane characteristics

and/or improve peritoneal dialysis for a given patient, wherein said peritoneal dialysis sampling system comprises a series of sampling containers, pumping means and a series of valves adapted to direct a certain quantity of each fluid sample to a specific sampling container,

a supplying line and supplying means for supplying dialysis fluid to a peritoneal cavity, a draining line, draining means for draining the fluid from said peritoneal cavity, connecting means for allowing a connection to a Y-site on the draining line which is situated between the patient peritoneum and the draining means of the peritoneal dialysis system, and
wherein said pumping means is of a peristaltic type.

For at least the foregoing reasons, the rejection should be withdrawn, i.e., it is defective and does not present a prima facie case of obviousness of dependent claims 7, 10 and 11.

Applicant respectfully submits that this application is in condition for allowance. A notice to that effect is earnestly solicited.

If the Examiner has any questions concerning this case, the undersigned may be contacted at 703-816-4009.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Duane M. Byers/

Duane M. Byers
Reg. No. 33,363

DMB:lfo
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000